



JC10 Rec'd PCT TO 19 JUL 2005 PCT #3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Tetsushi TAGUCHI et al.**

Group Art Unit: **Not yet assigned**

Serial No.: **10/527,694**

Examiner: **Not yet assigned**

Filed: **March 11, 2005**

Confirmation No.: **Not yet assigned**

For: **BIOLOGICAL LOW-MOLECULAR WEIGHT DERIVATIVES**

Attorney Docket Number: **052203**

Customer Number: **38834**

SUBMISSION OF ENGLISH TRANSLATION OF IPER

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

July 19, 2005

Sir:

Submitted herewith is an English translation of the International Preliminary Examination Report for the above-identified U.S. patent application. Please note that the cited references of the International Preliminary Examination Report were previously filed with the Information Disclosure Statement on March 11, 2005.

If any additional fees are due in connection with this submission, please charge our Deposit Account No. 50-2866.

Respectfully submitted,

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Enclosure: Form PCT/IB/338

From the INTERNATIONAL BUREAU

PCTNOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 72.2)

To:

NISHI, Yoshiyuki
Nishi Patent Office
Suite 211, 26-32, Nakahara 4-chome
Isogo-ku
Yokohama-shi, Kanagawa 235-0036
JAPONDate of mailing (*day/month/year*)
26 May 2005 (26.05.2005)Applicant's or agent's file reference
03-W-19**IMPORTANT NOTIFICATION**International application No.
PCT/JP2003/011669International filing date (*day/month/year*)
11 September 2003 (11.09.2003)

Applicant

NATIONAL INSTITUTE FOR MATERIALS SCIENCE et al

1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

2. Transmittal of the copy of the translation to the elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

CA, CN, EP

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

US

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO
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Translation

PATENT COOPERATION TREATY

PCT/JP2003/011669



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 03-W-19	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/011669	International filing date (day/month/year) 11 September 2003 (11.09.2003)	Priority date (day/month/year) 11 September 2002 (11.09.2002)
International Patent Classification (IPC) or national classification and IPC C07D 207/46, C08J 3/24 // A61L 27/18, 26/00		
Applicant NATIONAL INSTITUTE FOR MATERIALS SCIENCE		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>3</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand 12 April 2004 (12.04.2004)	Date of completion of this report 01 October 2004 (01.10.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/011669

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☐ The international application as originally filed/furnished
- ☒ the description:
- pages _____ 1-12 _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- pages _____ 5-7 _____, as originally filed/furnished
- pages* _____, as amended (together with any statement) under Article 19
- pages* _____ 1, 4, 8-11 _____ received by this Authority on _____ 27 August 2004 (27.08.2004)
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☒ the claims, Nos. _____ 2-3 _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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International application No.

PCT/JP 03/11669

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	4-11	YES
	Claims	1	NO
Inventive step (IS)	Claims	4-11	YES
	Claims	1	NO
Industrial applicability (IA)	Claims	1, 4-11	YES
	Claims		NO

2. Citations and explanations

Document 1: JP 61-69759 A

Document 2: WO 01/91814 A

Document 3: Journal of Organic Chemistry, 1996, 61 (24),
pp. 8496-8499

The invention that is set forth in claim 1 lacks novelty in the light of document 3 cited in the international search report. Document 3 presents 2-tert-butyl 1,3-di-N-succinimidyl citrates, and indicates that citrate, which is to say citric acid, is present in the citric acid cycle. Thus, the abovementioned compounds that are presented in document 3 can be said to be citric acid derivatives to which two N-hydroxysuccinimide molecules have been fused by means of condensation; therefore, the compounds in the invention that is set forth in claim 1 are the same as the compounds that are presented in document 3. Meanwhile, in the written response the applicant asserts that "the low-molecular weight biological derivatives that are set forth in claim 1 are limited to 'low-molecular weight biological derivatives characterized in that after application within an organism, the derivatives are hydrolysed and react with biopolymers in the organism.'...Document 3 presents '2-tert-butyl 1,3-di-N-succinimidyl citrates,' but does not make

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any disclosures pertaining to the properties, the applications or the like thereof, and...does not make any disclosures pertaining to the technical characteristics of the invention that is set forth in claim 1..." However, the abovementioned compounds that are presented in document 3 are the same as the compounds in the invention that is set forth in claim 1; therefore, naturally, they must exhibit the property whereby "after application within an organism, the derivatives are hydrolysed and react with biopolymers in the organism."

The inventions that are set forth in claims 4-11 are not disclosed or suggested in documents 1-3 cited in the international search report; therefore, they are novel and involve an inventive step.